

IN THE CLAIMS:

1. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) reducing the residual solvent content of a biological material to a level effective to protect said biological material from said ionizing radiation; and

(ii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to step (ii).

2. (Original) The method according to claim 1, wherein said solvent is water.

3. (Original) The method according to claim 1, wherein said solvent is an organic solvent.

β1 4. (Original) The method according to claim 1, wherein said biological material is blood or a component of blood.

5. (Original) The method according to claim 1, wherein said biological material is a proteinaceous material.

6. (Original) The method according to claim 5, wherein said proteinaceous material is a component of blood.

7. (Original) The method according to claim 1, wherein said biological material is a clotting factor.

8. (Original) The method according to claim 7, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

9. (Original) The method according to claim 1, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

10. (Original) The method according to claim 1, wherein said biological material is mammalian tissue or a component of mammalian tissue.

11. (Original) The method according to claim 1, wherein said biological material is a recombinantly-produced biological material.

B¹ 12. (Original) The method according to claim 1, wherein said biological material is a transgenic biological material.

13. (Original) The method according to claim 1, wherein said biological material is a food or a botanical product.

14. (Original) The method according to claim 1, wherein said ionizing radiation is gamma radiation.

15. (Original) The method according to claim 1, wherein said biological material is a carbohydrate or polysaccharide.

16. (Original) The method according to claim 1, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

17. (Original) The method according to claim 1, wherein said biological material is a product of cellular metabolism.

18. (Original) The method according to claim 1, wherein said effective rate is not more than about 3.0 kGy/hour.

19. (Original) The method according to claim 1, wherein said effective rate is more than about 3.0 kGy/hour.

20. (Original) The method according to claim 1, wherein said effective rate is not more than about 6.0 kGy/hour.

21. (Original) The method according to claim 1, wherein said effective rate is not more than about 18.0 kGy/hour.

B1 22. (Original) The method according to claim 1, wherein said effective rate is not more than about 30.0 kGy/hour.

23. (Original) The method according to claim 1, wherein said biological material is maintained in a low oxygen atmosphere.

24. (Original) The method according to claim 23, wherein said biological material is maintained in an argon atmosphere.

25. (Currently Amended) The method according to claim 1 ~~any one of claims 1-24~~, wherein said residual solvent content is reduced by lyophilization.

26. (Currently Amended) The method according to claim 1 ~~25~~, wherein said residual solvent content is less than about 2.0%.

27. (Currently Amended) The method according to claim 1 25, wherein said residual solvent content is less than about 1.0%.

28. (Currently Amended) The method according to claim 1 25, wherein said residual solvent content is less than about 0.5%.

29. (Cancelled)

30. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

B1 (i) adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids; and

(ii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material.

31. (Cancelled)

32. (Cancelled)

33. (Cancelled)

34. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) reducing the residual ~~moisture~~ solvent content of a biological material to a level effective to protect said biological material from said ionizing radiation;

(ii) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids; and

(iii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material.

35. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

B' (i) adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, polyhydric alcohols, rutin and other flavanoids;

(ii) reducing the residual ~~moisture~~ solvent content of said biological material to a level effective to protect said biological material from said ionizing radiation; and

(iii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material.

36. (New) The method according to claim 30, wherein said biological material is blood or a component of blood.

37. (New) The method according to claim 30, wherein said biological material is a proteinaceous material.

38. (New) The method according to claim 37, wherein said proteinaceous material is a component of blood.

39. (New) The method according to claim 30, wherein said biological material is a clotting factor.

40. (New) The method according to claim 39, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

41. (New) The method according to claim 30, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

42. (New) The method according to claim 30, wherein said biological material is mammalian tissue or a component of mammalian tissue.

43. (New) The method according to claim 30, wherein said biological material is a recombinantly-produced biological material.

44. (New) The method according to claim 30, wherein said biological material is a transgenic biological material.

45. (New) The method according to claim 30, wherein said biological material is a food or a botanical product.

46. (New) The method according to claim 30, wherein said ionizing radiation is gamma radiation.

47. (New) The method according to claim 30, wherein said biological material is a carbohydrate or polysaccharide.

48. (New) The method according to claim 30, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

49. (New) The method according to claim 30, wherein said biological material is a product of cellular metabolism.

50. (New) The method according to claim 30, wherein said effective rate is not more than about 3.0 kGy/hour.

51. (New) The method according to claim 30, wherein said effective rate is more than about 3.0 kGy/hour.

β' 52. (New) The method according to claim 30, wherein said effective rate is not more than about 6.0 kGy/hour.

53. (New) The method according to claim 30, wherein said effective rate is not more than about 18.0 kGy/hour.

54. (New) The method according to claim 30, wherein said effective rate is not more than about 30.0 kGy/hour.

55. (New) The method according to claim 30, wherein said biological material is maintained in a low oxygen atmosphere.

56. (New) The method according to claim 55, wherein said biological material is maintained in an argon atmosphere.

57. (New) The method according to claim 34, wherein said solvent is water.

58. (New) The method according to claim 34, wherein said solvent is an organic solvent.

59. (New) The method according to claim 34, wherein said biological material is blood or a component of blood.

60. (New) The method according to claim 34, wherein said biological material is a proteinaceous material.

61. (New) The method according to claim 60, wherein said proteinaceous material is a component of blood.

62. (New) The method according to claim 34, wherein said biological material is a clotting factor.

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63. (New) The method according to claim 62, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

64. (New) The method according to claim 34, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

65. (New) The method according to claim 34, wherein said biological material is mammalian tissue or a component of mammalian tissue.

66. (New) The method according to claim 34, wherein said biological material is a recombinantly-produced biological material.

67. (New) The method according to claim 34, wherein said biological material is a transgenic biological material.

68. (New) The method according to claim 34, wherein said biological material is a food or a botanical product.

69. (New) The method according to claim 34, wherein said ionizing radiation is gamma radiation.

70. (New) The method according to claim 34, wherein said biological material is a carbohydrate or polysaccharide.

71. (New) The method according to claim 34, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

72. (New) The method according to claim 34, wherein said biological material is a product of cellular metabolism.

B' 73. (New) The method according to claim 34, wherein said effective rate is not more than about 3.0 kGy/hour.

74. (New) The method according to claim 34, wherein said effective rate is more than about 3.0 kGy/hour.

75. (New) The method according to claim 34, wherein said effective rate is not more than about 6.0 kGy/hour.

76. (New) The method according to claim 34, wherein said effective rate is not more than about 18.0 kGy/hour.

77. (New) The method according to claim 34, wherein said effective rate is not more than about 30.0 kGy/hour.

78. (New) The method according to claim 34, wherein said biological material is maintained in a low oxygen atmosphere.

79. (New) The method according to claim 78, wherein said biological material is maintained in an argon atmosphere.

80. (New) The method according to claim 34, wherein said residual solvent content is reduced by lyophilization.

81. (New) The method according to claim 34, wherein said residual solvent content is less than about 2.0%.

82. (New) The method according to claim 34, wherein said residual solvent content is less than about 1.0%.

83. (New) The method according to claim 34, wherein said residual solvent content is less than about 0.5%.

84. (New) The method according to claim 35, wherein said solvent is water.

85. (New) The method according to claim 35, wherein said solvent is an organic solvent.

86. (New) The method according to claim 35, wherein said biological material is blood or a component of blood.

87. (New) The method according to claim 35, wherein said biological material is a proteinaceous material.

88. (New) The method according to claim 87, wherein said proteinaceous material is a component of blood.

89. (New) The method according to claim 35, wherein said biological material is a clotting factor.

90. (New) The method according to claim 89, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

91. (New) The method according to claim 35, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

92. (New) The method according to claim 35, wherein said biological material is mammalian tissue or a component of mammalian tissue.

93. (New) The method according to claim 35, wherein said biological material is a recombinantly-produced biological material.

94. (New) The method according to claim 35, wherein said biological material is a transgenic biological material.

95. (New) The method according to claim 35, wherein said biological material is a food or a botanical product.

96. (New) The method according to claim 35, wherein said ionizing radiation is gamma radiation.

97. (New) The method according to claim 35, wherein said biological material is a carbohydrate or polysaccharide.

98. (New) The method according to claim 35, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

99. (New) The method according to claim 35, wherein said biological material is a product of cellular metabolism.

100. (New) The method according to claim 35, wherein said effective rate is not more than about 3.0 kGy/hour.

101. (New) The method according to claim 35, wherein said effective rate is more than about 3.0 kGy/hour.

102. (New) The method according to claim 35, wherein said effective rate is not more than about 6.0 kGy/hour.

103. (New) The method according to claim 35, wherein said effective rate is not more than about 18.0 kGy/hour.

104. (New) The method according to claim 35, wherein said effective rate is not more than about 30.0 kGy/hour.

105. (New) The method according to claim 35, wherein said biological material is maintained in a low oxygen atmosphere.

106. (New) The method according to claim 105, wherein said biological material is maintained in an argon atmosphere.

107. (New) The method according to claim 35, wherein said residual solvent content is reduced by lyophilization.

108. (New) The method according to claim 35, wherein said residual solvent content is less than about 2.0%.

109. (New) The method according to claim 35, wherein said residual solvent content is less than about 1.0%.

110. (New) The method according to claim 35, wherein said residual solvent content is less than about 0.5%.

111. (New) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) reducing the residual solvent content of a biological material to a level effective to protect said biological material from said ionizing radiation;

B' (ii) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation; and

(iii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to step (iii).

112. (New) The method according to claim 111, wherein said solvent is water.

113. (New) The method according to claim 111, wherein said solvent is an organic solvent.

114. (New) The method according to claim 111, wherein said biological material is blood or a component of blood.

115. (New) The method according to claim 111, wherein said biological material is a proteinaceous material.

116. (New) The method according to claim 115, wherein said proteinaceous material is a component of blood.

117. (New) The method according to claim 111, wherein said biological material is a clotting factor.

118. (New) The method according to claim 117, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

119. (New) The method according to claim 111, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

120. (New) The method according to claim 111, wherein said biological material is mammalian tissue or a component of mammalian tissue.

121. (New) The method according to claim 111, wherein said biological material is a recombinantly-produced biological material.

122. (New) The method according to claim 111, wherein said biological material is a transgenic biological material.

123. (New) The method according to claim 111, wherein said biological material is a food or a botanical product.

124. (New) The method according to claim 111, wherein said ionizing radiation is gamma radiation.

125. (New) The method according to claim 111, wherein said biological material is a carbohydrate or polysaccharide.

126. (New) The method according to claim 111, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

127. (New) The method according to claim 111, wherein said biological material is a product of cellular metabolism.

128. (New) The method according to claim 111, wherein said effective rate is not more than about 3.0 kGy/hour.

129. (New) The method according to claim 111, wherein said effective rate is more than about 3.0 kGy/hour.

81 130. (New) The method according to claim 111, wherein said effective rate is not more than about 6.0 kGy/hour.

131. (New) The method according to claim 111, wherein said effective rate is not more than about 18.0 kGy/hour.

132. (New) The method according to claim 111, wherein said effective rate is not more than about 30.0 kGy/hour.

133. (New) The method according to claim 111, wherein said biological material is maintained in a low oxygen atmosphere.

134. (New) The method according to claim 133, wherein said biological material is maintained in an argon atmosphere.

135. (New) The method according to claim 111, wherein said residual solvent content is reduced by lyophilization.

136. (New) The method according to claim 111, wherein said residual solvent content is less than about 2.0%.

137. (New) The method according to claim 111, wherein said residual solvent content is less than about 1.0%.

138. (New) The method according to claim 111, wherein said residual solvent content is less than about 0.5%.

139. (New) The method according to claim 111, wherein said at least one stabilizer is an antioxidant.

140. (New) The method according to claim 111, wherein said at least one stabilizer is a free radical scavenger.

141. (New) The method according to claim 111, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids.

142. (New) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation;

(ii) reducing the residual solvent content of said biological material to a level effective to protect said biological material from said ionizing radiation; and

(iii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein at least one sensitizer is added to said biological material prior to step (iii).

143. (New) The method according to claim 142, wherein said solvent is water.

144. (New) The method according to claim 142, wherein said solvent is an organic solvent.

145. (New) The method according to claim 142, wherein said biological material is blood or a component of blood.

146. (New) The method according to claim 142, wherein said biological material is a proteinaceous material.

147. (New) The method according to claim 146, wherein said proteinaceous material is a component of blood.

148. (New) The method according to claim 142, wherein said biological material is a clotting factor.

149. (New) The method according to claim 148, wherein said clotting factor is selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor and Fibrinogen.

150. (New) The method according to claim 142, wherein said biological material is selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G and mixtures of one or more immunoglobulins.

151. (New) The method according to claim 142, wherein said biological material is mammalian tissue or a component of mammalian tissue.

152. (New) The method according to claim 142, wherein said biological material is a recombinantly-produced biological material.

153. (New) The method according to claim 142, wherein said biological material is a transgenic biological material.

154. (New) The method according to claim 142, wherein said biological material is a food or a botanical product.

155. (New) The method according to claim 142, wherein said ionizing radiation is gamma radiation.

156. (New) The method according to claim 142, wherein said biological material is a carbohydrate or polysaccharide.

B1 157. (New) The method according to claim 142, wherein said biological material is selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

158. (New) The method according to claim 142, wherein said biological material is a product of cellular metabolism.

159. (New) The method according to claim 142, wherein said effective rate is not more than about 3.0 kGy/hour.

160. (New) The method according to claim 142, wherein said effective rate is more than about 3.0 kGy/hour.

161. (New) The method according to claim 142, wherein said effective rate is not more than about 6.0 kGy/hour.

162. (New) The method according to claim 142, wherein said effective rate is not more than about 18.0 kGy/hour.

163. (New) The method according to claim 142, wherein said effective rate is not more than about 30.0 kGy/hour.

164. (New) The method according to claim 142, wherein said biological material is maintained in a low oxygen atmosphere.

165. (New) The method according to claim 164, wherein said biological material is maintained in an argon atmosphere.

166. (New) The method according to claim 142, wherein said residual solvent content is reduced by lyophilization.

Bl 167. (New) The method according to claim 142, wherein said residual solvent content is less than about 2.0%.

168. (New) The method according to claim 142, wherein said residual solvent content is less than about 1.0%.

169. (New) The method according to claim 142, wherein said residual solvent content is less than about 0.5%.

170. (New) The method according to claim 142, wherein said at least one stabilizer is an antioxidant.

171. (New) The method according to claim 142, wherein said at least one stabilizer is a free radical scavenger.

172. (New) The method according to claim 142, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids.

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